

EXHIBIT 3
9/20/2024 Letter from Government to Defendants



United States Department of Justice
Consumer Protection Branch
450 Fifth Street, N.W., Suite 6400
Washington, D.C. 20001

September 20, 2024

By Email

Joseph J. Mahady, Esq.
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Re: United States v. AmerisourceBergen, et al., Civ. No. 22-5209 (E.D. Pa.)

Dear Counsel:

We write in response to your letter dated September 13, 2024.

Preliminarily, we reject your suggestion that the Government has been unclear about our position on the internal DEA documents we are willing to produce, or that we are now withholding documents that we previously agreed to produce. We have been clear from the outset that non-public, internal DEA analyses of caselaw and discussions of potential new regulations are not appropriate subjects of discovery. We have in fact repeatedly directed you to caselaw that soundly supports the irrelevance of these materials, and we do not understand how you could have believed that we intended to produce them based on our prior communications. It is not impossible Defendants may have been confused, but Defendants' suggestion that the Government is withholding documents we agreed to produce is entirely unwarranted.

Moreover, to the extent Defendants were confused about specific details of our position, Defendants had months to seek clarification. The questions Defendants raised in their September 13 letter could have easily been clarified in May. Instead of doing so, Defendants opted to rush to court (over our objection) to complain about the Government's discovery positions, with a premature, ill-defined request—as rightfully noted by the Court. *See* Dkt. No. 82 at 2 (“[T]he Court remains unsure what exactly Amerisource wants the Court to do.”). And after the Court denied Defendants' request for discovery, Defendants waited over a month to even re-engage with us on this issue. Thus, even accepting *arguendo* Defendants' claim that the Government only clarified certain nuances of its position last week, that would be a problem of Defendants' own making.

To again reiterate our position, the Complaint alleges that Defendants unlawfully failed to report suspicious orders of controlled substances, including in connection with Defendants' sales of enormous quantities of opioids to customers that engaged in proven criminal schemes to divert

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opioids.¹ The relevant questions at issue following the Court's motion to dismiss decision are: (1) on how many occasions Defendants failed to report suspicious orders of controlled substances in violation of 21 U.S.C. § 832(a)(3); (2) whether such violations of 21 U.S.C. § 832(a)(3) were committed with a *mens rea* violating 21 U.S.C. § 842(a)(5); and (3) the appropriate relief. Pursuant to the Federal Rules of Civil Procedure, document discovery in this case encompasses the production of materials germane to those inquiries, but not irrelevant materials.

We agree that what DEA told Defendants about how to interpret the suspicious order reporting laws is relevant to ascertaining the *mens rea* with which Defendants violated § 832(a)(3). We also recognize that Defendants have a tenable argument that what DEA told third parties (such as industry groups or other registrants) about the meaning of the suspicious order reporting laws could also be relevant to ascertaining Defendants' *mens rea*, since guidance DEA gave others could have been conveyed to Defendants. Accordingly, we have agreed to produce² correspondence between DEA and external parties regarding the interpretation of the suspicious order reporting laws (such as emails and letters).

For the same reasons, we agreed to produce internal DEA documents reflecting the contents of communications between DEA and external parties regarding the same. In our recent

¹ See, e.g., Application for Permission to Enter Plea of Guilty, *U.S. v. Dunn Meadow LLC*, Crim. No. 22-517 (D.N.J. Aug. 3, 2022), ECF No. 4 (Defendants' customer pleading guilty to conspiracy to unlawfully distribute controlled substances including fentanyl in violation of the CSA); Plea Agreement, *U.S. v. Griffith*, Crim. No. 21-2 (M.D.Tenn. Aug. 26, 2021), ECF No. 18 (pharmacist in charge of Defendants' customer pleading guilty to conspiracy to unlawfully distribute controlled substances); Plea Agreement, *U.S. v. Polston*, Crim. No. 19-6 (M.D.Tenn. Mar. 23, 2021), ECF No. 64 (pharmacist in charge of Defendants' customer pleading guilty to conspiracy to unlawfully distribute controlled substances); Plea Agreement, *U.S. v. Ntukogu*, Crim. No. 19-82 (E.D.Cal. Apr. 23, 2024), ECF No. 144 (Defendants' customer pleading guilty to conspiracy to unlawfully distribute "29,999 KGs of converted drug weight consisting of oxycodone and hydrocodone pills").

² All commitments to produce documents included in this letter are limited to non-privileged documents identified pursuant to agreed-upon search parameters (e.g., custodians, time periods, search terms). Such commitments incorporate and do not waive the Government's objections to Defendants' Requests on grounds besides those addressed in this letter, nor do they alter the Government's previously conveyed positions regarding custodians, non-custodial data sources, customer discovery, time periods, or any other matters unrelated to those addressed in this letter. Moreover, commitments to produce certain documents should not be taken as representations that such documents exist or will be identified pursuant to agreed-upon search parameters, and merely reflect a commitment to produce non-privileged documents if they exist and are identified pursuant to the agreed-upon search parameters. References to "privileged documents" mean documents protected from disclosure by any applicable privilege, protection, or exemption, as described in General Statement No. 6 in the Government's Objections and Responses to Defendants' First Set of Requests for Production of Documents.

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discussion, you identified a perceived ambiguity with this category of documents (described under the heading “Internal DEA communications relating to external communications” in our May 17 letter). We think our position was clear from the discussion in our prior letter, but to clarify once again, when we referred to external “communications,” we intended to encompass specific direct communications with external parties, not broadly applicable regulations or legal decisions issued in other cases. Moreover, when we referred to documents that “relate” to such communications, we intended to encompass documents that summarize or discuss specific communications with external parties, not all documents broadly concerning a topic that eventually was addressed in an externally-disseminated document. Accordingly, we would produce notes or summaries of meetings and phone calls with a distributor or industry group relating to the interpretation of the suspicious order reporting laws, or other documents reflecting the content of a direct communication with an external party. We would not produce all internal DEA documents discussing potential amendments to a DEA regulation simply because DEA eventually issued a notice of proposed rulemaking concerning the regulation.

Finally, we also recognize that internal DEA communications regarding the application of the suspicious order reporting laws to the conduct at issue in this case—in particular, communications regarding the application of those laws to Defendants’ suspicious order monitoring and reporting practices—are potentially relevant, and we have thus agreed to produce such materials.³

However, as we have repeatedly explained, internal DEA documents containing DEA employees’ non-public commentary on the meaning of the suspicious order reporting laws or their non-public thoughts on potential new statutes or regulations are not relevant outside the limited circumstances set forth above.⁴ That is because such documents cannot inform the

³ In your letter, you contend that the *Masters* decision and DEA’s Notice of Proposed Rulemaking in 2020 involve the “facts of this case” and therefore claim you are surprised that we do not intend to produce all internal documents discussing these topics. Again, we believe the scope of documents we intend to produce was evident in our prior letter; when we refer to documents concerning the “facts in this case” or “conduct at issue” we refer to DEA documents concerning Defendants’ suspicious order monitoring and reporting practices, and the application of the suspicious order reporting laws to Defendants’ and their customers’ conduct associated with the violations at issue.

⁴ In our May 17 letter, we also agreed to meet and confer regarding the potential production of an additional category of internal DEA materials: internal communications from the custodial files of non-attorney DEA personnel whom Defendants contend provided them with direct and specific advice (as opposed to advice shared with industry members more broadly or publicly) regarding the interpretation of the suspicious order reporting laws that Defendants contend is inconsistent with the Government’s legal theory in the Complaint. However, since (1) Defendants have failed to identify any such DEA personnel, either in their interrogatory responses or any other communication in the past four months, and (2) during our last meet and confer, defense counsel clarified that Defendants’ grievance is not with specific advice Defendants received from DEA,

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Court's legal interpretative task, and they do not shed any light on the *mens rea* with which Defendants acted when they violated § 832(a)(3).

Our position is informed and amply supported by numerous on-point appellate and district court decisions that we have previously highlighted, including: *United States v. Farley*, 11 F.3d 1385, 1391 (7th Cir. 1993); *Consumer Fin. Prot. Bureau v. Navient Corp.*, Civ. No. 17-101, 2018 WL 2088760, at *4 (M.D. Pa. May 4, 2018); *United States v. Wisconsin Bell, Inc.*, Civ. No. 08-724, 2020 WL 13048895, at *2 (E.D. Wis. Oct. 29, 2020); *S.E.C. v. BankAtlantic Bancorp, Inc.*, 285 F.R.D. 661, 668 (S.D. Fla. 2012); and *United States v. Navistar Int'l Corp.*, 236 F. Supp. 3d 1049, 1057 (N.D. Ill. 2017). Moreover, just last month, another federal court denied a motion to compel production of irrelevant internal agency documents in yet another on-point decision drawing exactly the distinction the Government is drawing here. *See F.T.C. v. Amazon.com, Inc.*, Civ. No. 23-932, 2024 WL 3924583 (W.D. Wash. Aug. 22, 2024).

Defendants have refused to engage with this caselaw in either their written correspondence or our meet and confer conversations, instead continuing to accuse the government of silently withholding documents by making a “subjective, and self-serving assessment of ‘relevance.’” But we have been transparent about what we consider and do not consider to be relevant, and the persuasive opinions cited above (as well as the other law cited in our prior letters) make clear that the relevance distinctions we are drawing are entirely appropriate. It is Defendants who are making “self-serving” arguments divorced from applicable legal standards, in an effort to inappropriately use this litigation as an opportunity to explore all manner of irrelevant grievance.

We welcome further dialogue on the scope of internal DEA documents that should be produced in discovery, but such dialogue must be consistent with, and based on, the Federal Rules and applicable caselaw. For instance, in your September 13 letter, Defendants represent that it is “troubling” that communications from lower-level employees are not treated differently from communications from higher-level employees. But Defendants have not identified any caselaw that would support treating higher-level and lower-level employees differently, and we are not aware of any such law. To the extent Defendants can identify legal support for their position, we would be happy to consider it. However, we believe Defendants’ generalized complaints not based in law about the “troubling” nature of the Government’s well-founded discovery positions are both unproductive and inconsistent with the Federal Rules regarding the scope of discovery.

With those preliminary points established, we respond below to the specific questions posed in your letter, and address the Requests for Production that you identified:

Responses to Defendants’ Questions:

- *Q: Will the Government produce internal DEA communications that do not specifically reference Defendants that are otherwise responsive to these Requests?*

but rather what defense counsel described as DEA’s refusal to provide useful guidance, we believe this potential category is no longer at issue.

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- A: We have agreed to produce written correspondence between DEA and external parties regarding the interpretation of the suspicious order reporting laws (such as emails and letters) as well as internal DEA documents reflecting the contents of communications between DEA and external parties regarding the same (such as notes or summaries of meetings and phone calls). We have also agreed to produce internal DEA communications regarding the application of the suspicious order reporting laws to the conduct at issue in this case, such as communications regarding the legality of Defendants' suspicious order monitoring and reporting practices. Documents that fit within these parameters and are responsive to Defendants' requests but do not specifically reference Defendants will be produced. We do not otherwise intend to produce internal DEA communications relating to DEA employees' non-public statements regarding the interpretation of the suspicious order reporting laws.

- Q: *Will the Government produce internal DEA communications discussing the subject of communications that eventually went to third parties (e.g., the proposed 2020 amended regulation, Masters)?*
A: We have agreed to produce written correspondence between DEA and external parties regarding the interpretation of the suspicious order reporting laws (such as emails and letters) as well as internal DEA documents reflecting the contents of communications between DEA and external parties regarding the same (such as notes or summaries of meetings and phone calls). We will not produce internal correspondence regarding the drafting of the published notice of proposed rulemaking (NPRM) referenced by Defendants. We have explained at length why such materials are not relevant; the confidential considerations of DEA policymakers and attorneys that went into the drafting of that NPRM have no relevance to ascertaining the *mens rea* with which Defendants violated § 832(a)(3) (as well as likely being almost exclusively privileged). For similar reasons, we would not produce purely internal correspondence relating to published legal opinions like the *Masters* decisions, or to written external guidance. The relevant characteristic of such written materials is the impact they may have had on Defendants, and non-public internal discussions that went into the drafting of such materials could not have had any such impact. As discussed above, by agreeing to produce documents relating to external DEA communications, we meant documents summarizing or discussing direct communications between DEA and third parties, not all documents concerning a topic that eventually may have also been addressed in a public document.

- Q: *Will the Government produce internal DEA communications regarding the interpretation of the SOR laws from someone who did not communicate directly with Defendants (e.g., communicated with another third-party or communicated with someone who ultimately did communicate with Defendants)?*
- A: We have agreed to produce internal DEA documents reflecting the contents of correspondence between DEA and external parties including but not limited to Defendants regarding the interpretation of the suspicious order reporting laws,

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subject to the parties' agreements on custodians and search parameters. Thus, to the extent one of our agreed custodians has internal documents of the type we have agreed to produce, we would produce such documents irrespective of whether the particular custodian communicated directly with Defendants. We would not produce all internal communications relating to the suspicious order reporting laws from every DEA employee who ever communicated with a third party about suspicious orders.

- *Q: Does the Government's calculus change on what it is withholding based on the person's position at DEA, and if so, where is the Government drawing the line?*
- *A:* No. Whether the DEA employee at issue is the Deputy Assistant Administrator for Diversion, an Office of Chief Counsel Attorney, or a line-level Diversion Investigator, their non-public thoughts on the suspicious order reporting laws and potential amendments thereto are not relevant to assessing how many times Defendants violated § 832(a)(3) or their *mens rea* in doing so, outside of the limited circumstances described above. The caselaw is clear that though formal published agency interpretations can be entitled to deference, the informal non-public opinions of even top agency officials on matters of statutory interpretation are not entitled to any interpretive weight. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004). Similarly, whether a supervisory or line-level employee communicated with external parties regarding the meaning of suspicious order reporting laws, we would regard documents reflecting those communications as within the scope of what we are agreeing to produce, as described above.

Positions on Requests in Defendants' First Set of Requests for Production:

- *RFP 2 - From 2014 through the filing of the complaint, all DEA Documents regarding the meaning of Suspicious Order, including but not limited to any ambiguity, vagueness, imprecision, or subjectivity in the meaning or application of the term.*
- *Response:* We have agreed to produce public documents and external correspondence responsive to this request. We have also agreed to produce internal documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. That would include, for example, notes from a meeting in which DEA discussed the meaning of "suspicious order" with an external party (to the extent such documents exist, are not privileged, and are identified by our searches). We have also agreed to produce internal documents responsive to this request if they relate to the conduct at issue in this case. We do not otherwise agree to produce internal documents responsive to this request, which are not relevant.
- *RFP 3 - From 2007 through the filing of the complaint, all DEA Documents regarding whether or how the Suspicious Order Monitoring and Reporting*

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Obligations apply to “orders of interest” (or other similar terminology used to describe orders that hit a Registrant’s threshold, parameter, or algorithm).

- Response: We have agreed to produce public documents and external correspondence responsive to this request. We have also agreed to produce internal documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. We have also agreed to produce internal documents responsive to this request if they relate to the conduct at issue in this case. That would include, for example, non-privileged internal documents discussing the application of § 832(a)(3) to Defendants’ order monitoring programs and orders Defendants’ policies characterize as “orders of interest” (to the extent such documents exist and are identified by our searches). We do not otherwise agree to produce internal documents responsive to this request, which are not relevant.

- *RFP 7 – All DEA Documents from 2015 through the filing of the complaint regarding: a. the DEA’s interpretation or understanding of the Masters Decisions; b. any Rule You contend was created or otherwise established by either of the Masters Decisions; c. the DEA’s internal or external guidance or training materials regarding the Masters Decisions; and d. requests to DEA for guidance about the Masters Decisions (including the NACDS Letter), and the DEA’s response (or lack thereof) to such requests.*

- Response: We have agreed to produce public documents and external correspondence responsive to this request. That would include, for example, any requests to DEA for guidance from external parties about the *Masters* decisions, and written correspondence with industry members about the consequences of the *Masters* decisions’ interpretation of the suspicious order reporting laws on other distributors (to the extent such documents exist and are identified by our searches). We have also agreed to produce internal documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. That would include, for example, notes from a meeting in which DEA discussed the import of the *Masters* decisions on the interpretation of the suspicious order reporting laws with an industry group representative (to the extent such documents exist and are identified by our searches). We have also agreed to produce internal documents responsive to this request if they relate to the conduct at issue in this case. We do not otherwise agree to produce internal documents responsive to this request, which are not relevant (as well as likely being almost exclusively privileged). For example, we will not produce purely internal legal analyses or internal Office of Chief Counsel guidance regarding *Masters*, internal communications relating to the drafting of a subsequently published external communication regarding *Masters*, or internal communications regarding the preparation and issuance of the Administrator’s *Masters* decision.

- *RFP 9 - From 2007 through the filing of the complaint, all Communications between the DEA and any industry group or trade association, including but not*

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limited to the Healthcare Distribution Management Association, Healthcare Distribution Alliance, and National Association of Chain Drug Stores, regarding the Suspicious Order Monitoring and Reporting Obligations, what constitutes a Suspicious Order, how to design and operate a suspicious order monitoring system, and/or any other diversion control obligations for distributors of controlled substances, and all Documents regarding such Communications including but not limited to notes or summaries of meetings or phone calls.

- Response: We have agreed to produce public documents and external correspondence responsive to this request. That would include correspondence between DEA and industry groups sought by the request. We have also agreed to produce internal documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. That would not include non-final drafts of written external correspondence, final drafts of which will be produced in this case, since internal communications that went into the drafting of such materials could not have had any impact on Defendants and thus are not relevant (as well as likely being privileged).
- *RFP 12 – All DEA, DOJ, OIG, GAO, and OMB Documents from 2014 through the filing of the complaint regarding the 2020 SOR Notice, including but not limited to: a. All drafts of the 2020 SOR Notice; b. All calculations of estimated times, costs, and reports of Suspicious Orders as set forth in the 2020 SOR Notice; c. the drafting, formulation, internal approvals, and issuance of the 2020 SOR Notice; d. all comments received in response to the 2020 SOR Notice and all Documents regarding such comments; e. all Communications regarding the 2020 SOR Notice with any other branch, agency, or instrumentality of the United States, including but not limited to Congress, DOJ, GAO, OIG, and OMB, and all Documents regarding such Communications; f. the timing of the issuance of the 2020 SOR Notice, including the reasons for any delays; and g. the status of the proposed rule announced by the 2020 SOR Notice.*
- Response: We have agreed to produce public DEA documents and external correspondence responsive to this request. We have also agreed to produce internal DEA documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. We do not otherwise agree to produce internal documents responsive to this request, which are not relevant. As we have repeatedly explained, this case involves Defendants' violations of 21 U.S.C. §§ 832(a)(3), 842(a)(5). The Notice of Proposed Rulemaking at issue, 85 Fed. Reg. 69,282, (the "2020 NPRM") is only relevant to this case to whatever limited extent the text of the 2020 NPRM and external communications relating to it shed light on the *mens rea* with which Defendants violated § 832(a)(3).
- *RFP 67 - All DEA Documents from 2007 through the filing of the complaint relating to DEA statements to Registrants not to report every order that is flagged by a*

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Registrant's suspicious order monitoring system, including but not limited to at the May 10-11, 2016 HDMA conference.

- Response: We have agreed to produce public documents and external correspondence responsive to this request. That would include, for example written correspondence instructing registrants not to report flagged orders (to the extent such documents exist and are identified by our searches). We have also agreed to produce internal documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. That would include, for example, non-privileged notes or summaries regarding anything said about the suspicious order reporting laws during the May 10-11, 2016 HDMA conference (to the extent such documents exist and are identified by our searches). We have also agreed to produce internal documents responsive to this request if they relate to the conduct at issue in this case. We do not otherwise agree to produce internal documents responsive to this request.

Positions on Requests in Defendants' Second Set of Requests for Production:

- *RFP 3 - All Documents and Communications at DEA, including internal DEA communications, related to the National Association of Chain Drug Stores' letter to DEA dated February 6, 2018 requesting clarification on the 2017 D.C. Circuit Court opinion issued in Masters Pharmaceutical, inc. v. Drug Enforcement Administration.*
- Response: We have agreed to produce public documents and external correspondence responsive to this request. That would include the correspondence dated February 6, 2018 sought by the request, and any written response from DEA (to the extent such documents exist and are identified by our searches). We have also agreed to produce internal documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. We do not agree to produce other internal DEA communications relating to the letter at issue, such as purely internal DEA discussions of whether to issue a written response to the letter at issue. Such internal DEA communications (to the extent they exist) would not be relevant to ascertaining the *mens rea* with which Defendants violated § 832(a)(3).
- *RFP 7 - All Documents and Communications at DEA, including internal DEA communications, related to a July 8, 2010 letter from HDMA to DEA.*
- Response: We have agreed to produce public documents and external correspondence responsive to this request. That would include the correspondence dated July 8, 2010 sought by the request, and any written response from DEA (to the extent such documents exist and are identified by our searches). We have also agreed to produce internal documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. We do not agree to

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produce other internal DEA communications relating to the letter at issue, such as internal DEA discussions of whether to issue a written response to the letter at issue. Such internal DEA communications (to the extent they exist) would not be relevant; DEA's purely internal considerations in deciding whether and how to respond to a letter in 2010 plainly are not relevant to determining whether Defendants violated a statute enacted by Congress 8 years later, or their *mens rea* in doing so.

- *RFP 8 - All Documents and Communications at DEA, including internal DEA communications, related to the December 7, 2010 meeting between DEA and the Healthcare Distribution Management Association ("HDMA"), the scheduled July 31, 2013 meeting between DEA and HDMA that was cancelled by DEA, and questions the HDMA submitted to DEA on June 1, 2011 and July 2, 2013.*
- Response: We have agreed to produce public documents and external correspondence responsive to this request. We have also agreed to produce internal documents reflecting the contents of communications between DEA and external parties (such as notes or summaries of meetings and phone calls) relating to the subject matter of this request. That would include copies of any presentations DEA presented at the 2010 meeting, or notes taken regarding that meeting (to the extent such documents exist and are identified by our searches). We do not agree to produce other internal DEA communications responsive to this request, such as internal DEA discussions of whether to cancel a meeting that did not occur and at which no information was conveyed to Defendants or anyone else. Such internal DEA communications (to the extent they exist) would not be relevant; DEA's internal considerations in deciding, *e.g.*, whether to hold a meeting in 2013 plainly are not relevant to determining whether Defendants violated a statute enacted by Congress 5 years later, or their *mens rea* in doing so.
- *RFP 9 - All Documents and Communications at DEA, including internal DEA communications, related to a December 19, 2011 presentation by HDMA to DEA.*
- Response: Please see our response to RFPs 3, 7, and 8.
- *RFP 11- All Documents and Communications at DEA, including internal DEA communications, related to the Distributor Initiative Meeting held at National Harbor on October 22, 2013.*
- Response: Please see our response to RFPs 3, 7, and 8.
- *RFP 17 - All Documents and Communications at DEA, including internal DEA communications, related to a conversation between HDMA and Lou Milione of DEA on or about November 13, 2015.*
- Response: Please see our response to RFPs 3, 7, and 8.
- *RFP 18 - All Documents and Communications at DEA, including internal DEA communications, related to a meeting between HDMA and DEA on February 29, 2016.*

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- Response: Please see our response to RFPs 3, 7, and 8.
- *RFP 19 - All Documents and Communications at DEA, including internal DEA communications, related to the DEA Distributor Conference on May 10-11, 2016.*
- Response: Please see our response to RFPs 3, 7, and 8.
- *RFP 20 - All Documents and Communications at DEA, including internal DEA communications, related to the Distributor Initiative Briefing in North Carolina on August 21, 2017.*
- Response: Please see our response to RFPs 3, 7, and 8.
- *RFP 21 - All Documents and Communications at DEA, including internal DEA communications, related to an HDA conference attended by DEA on or about March 11, 2019.*
- Response: Please see our response to RFPs 3, 7, and 8.
- *RFP 23 - All Communications between DEA and Registrants regarding In re Masters Pharm., Inc., 80 Fed. Reg. 55418, 55477-78 (Drug Enf't Admin. 2015), pet. for review denied sub nom. Masters Pharm., Inc. v. DEA, 861 F.3d 206 (D.C. Cir. 2017), including all internal DEA communications regarding Masters' impact on Registrants' obligations under 21 C.F.R. § 1301.74.*
- Response: Please see our response to RFP 7 of Defendants' First Set of Requests for Production, of which this RFP is duplicative.
- *RFP 25 - All Communications related to In re Nat'l Prescription Opiate Litig., MDL No. 2804, 2019 U.S. Dist. LEXIS 140020, at *61-64, 71-72 (N.D. Ohio Aug. 19, 2019), including internal DEA Communications, Communications with Registrants, and Communications with third parties, including but not limited to Communications with counsel for Plaintiffs.*
- Response: We have agreed to produce public documents and external correspondence discussing the pin cited portion of the opinion cited in this request, which contains that court's interpretation of 21 C.F.R. § 1301.74. We have also agreed to produce internal documents reflecting the contents of communications between DEA and registrants or associated parties discussing the same (such as notes or summaries of meetings and phone calls). We do not agree to produce other internal DEA communications relating to this opinion, such as internal Office of Chief Counsel analyses of the opinion (to the extent they exist). We also do not agree to otherwise produce all correspondence regarding this litigation (as distinct from correspondence relating to the portion of the relevant opinion construing § 1301.74) for reasons we have addressed elsewhere.
- *RFP 26 - All Communications related to City & Cnty. of S.F. v. Purdue Pharma L.P., 491 F. Supp. 3d 610, 631-32 (N.D. Cal. 2020), including internal DEA Communications, Communications between DEA and Registrants, and*

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Communications between DEA and third parties, including but not limited to Communications with counsel for Plaintiffs.

- Response: Please see our response to RFP 25.
- *RFP 27 - All Communications related to Cherokee Nation v. McKesson Corp., 529 F. Supp. 3d 1225, 1235 (E.D. Okla. 2021), including internal DEA Communications, Communications between DEA and Registrants, and Communications between DEA and third parties, including but not limited to Communications with counsel for Plaintiffs.*
- Response: Please see our response to RFP 25.

* * * *

We are willing to continue discussions on these matters, especially if you have questions regarding the scope of our production commitments or are interested in engaging in a discussion of how the law set forth in the cases we have cited applies here. Indeed, we believe the Court likely contemplated more of a back-and-forth effort to define the scope of relevant materials under the applicable law than Defendants have been willing to take part in so far. However, it is your choice how to proceed.

Sincerely,

/s/ Michael J. Wadden

Michael J. Wadden
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch

cc: Counsel of Record (by e-mail)